1 Identification

- **Product identifier**
  - **Trade name:** Consepsis™, Consepsis™ V
  - **Article number:** 10772, 10796
  - **Index number:** SDS 33-001.10
  - **Application of the substance / the mixture:** Professional Dental 2% Chlorhexidine Gluconate Solution

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**
    Ultradent Products Inc.
    505 W. Ultradent Drive (10200 S)
    South Jordan, UT 84095-3942
    USA
    onlineordersupport@ultradent.com
  - **Information department:** Customer Service
  - **Emergency telephone number:**
    CHEMTREC (NORTH AMERICA): (800) 424-9300
    (INTERNATIONAL): +(703) 527-3887

2 Hazard(s) identification

- **Classification of the substance or mixture**
  - ![GHS02 Flame](image)
    Flam. Liq. 3 H226 Flammable liquid and vapor.
  - ![GHS08 Health hazard](image)
    Repr. 2 H361 Suspected of damaging fertility or the unborn child.
    STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.
  - ![GHS07](image)
    Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements**
  Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS02, GHS07, GHS08
- **Signal word** Warning
- **Hazard-determining components of labeling:**
  - Dimethicone
  - Oils, Peppermint
- **Hazard statements**
  - Flammable liquid and vapor.
  - May cause an allergic skin reaction.
  - Suspected of damaging fertility or the unborn child.
  - May cause damage to organs through prolonged or repeated exposure.
Precautionary statements
If medical advice is needed, have product container or label at hand.
Keep out of reach of children.
Read label before use.
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Keep container tightly closed.
Ground/bond container and receiving equipment.
Use explosion-proof electrical/ventilating/lighting/equipment.
Use only non-sparking tools.
Take precautionary measures against static discharge.
Do not breathe dust/fume/gas/mist/vapors/spray.
Contaminated work clothing must not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF exposed or concerned: Get medical advice/attention.
Get medical advice/attention if you feel unwell.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.
In case of fire: Use for extinction: CO2, powder or water spray.
Store in a well-ventilated place. Keep cool.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:

NFPA ratings (scale 0 - 4)

Health = 0
Fire = 3
Reactivity = 0

HMIS-ratings (scale 0 - 4)

HEALTH 0
FIRE 3
REACTIVITY 0

Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

Composition/information on ingredients

Chemical characterization: Mixtures
Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 Ethyl Alcohol</td>
<td>&gt;10 - ≤20%</td>
</tr>
<tr>
<td>25322-68-3 Polyethylene Glycol</td>
<td>&gt;10 - ≤15%</td>
</tr>
<tr>
<td>Dimethicone</td>
<td>&lt;3%</td>
</tr>
<tr>
<td>18472-51-0 Chlorhexidine Gluconate</td>
<td>≤2.5%</td>
</tr>
</tbody>
</table>
4 First-aid measures

- Description of first aid measures
  - General information:
    Immediately remove any clothing soiled by the product.
    Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
  - After inhalation:
    Supply fresh air and to be sure call for a doctor. 
    In case of unconsciousness place patient stably in side position for transportation.
  - After skin contact:
    Immediately wash with water and soap and rinse thoroughly.
  - After eye contact:
    Rinse opened eye for several minutes under running water.
  - After swallowing:
    If symptoms persist consult doctor.
  - Information for doctor:
    Most important symptoms and effects, both acute and delayed No further relevant information available.
    Indication of any immediate medical attention and special treatment needed
    No further relevant information available.

5 Fire-fighting measures

- Extinguishing media
  - Suitable extinguishing agents:
    CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - For safety reasons unsuitable extinguishing agents: Water with full jet
  - Special hazards arising from the substance or mixture
    During heating or in case of fire poisonous gases are produced.

- Advice for firefighters
  - Protective equipment: Mouth respiratory protective device.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
  - Mount respiratory protective device.
    Wear protective equipment. Keep unprotected persons away.
  - Environmental precautions: Do not allow to enter sewers/ surface or ground water.
  - Methods and material for containment and cleaning up:
    Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
    Dispose contaminated material as waste according to item 13.
    Ensure adequate ventilation.

- Reference to other sections
  - See Section 7 for information on safe handling.
  - See Section 8 for information on personal protection equipment.
  - See Section 13 for disposal information.

- Protective Action Criteria for Chemicals
  - PAC-1:
    | 64-17-5 Ethyl Alcohol | 1,800 ppm |
    | 25322-68-3 Polyethylene Glycol | 30 mg/m³ |
7 Handling and storage

- Handling:
- Precautions for safe handling
  Ensure good ventilation/exhaustion at the workplace.
  :Open and handle receptacle with care.
  Prevent formation of aerosols.
- Information about protection against explosions and fires:
  Keep ignition sources away - Do not smoke.
  Protect against electrostatic charges.
  Keep respiratory protective device available.
- Conditions for safe storage, including any incompatibilities
- Storage:
  Requirements to be met by storerooms and receptacles: No special requirements.
  Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
  See product labelling.
  Keep receptacle tightly sealed.
- Specific end use(s) Professional Dental 2% Chlorhexidine Gluconate Solution

8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see item 7.
- Control parameters
- Components with limit values that require monitoring at the workplace:
  The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
  At this time, the other constituents have no known exposure limits.
  
  64-17-5 Ethyl Alcohol
  - PEL Long-term value: 1900 mg/m³, 1000 ppm
  - REL Long-term value: 1900 mg/m³, 1000 ppm
  - STEL Short-term value: 1000 mg/m³
  - TLV Short-term value: 1880 mg/m³, 1000 ppm
  - TWA Short-term value: 1900 mg/m³

  25322-68-3 Polyethylene Glycol
  - WEEL Long-term value: 10 mg/m³
    (H): MW>200

- Additional information: The lists that were valid during the creation were used as basis.
· Exposure controls
· Personal protective equipment:
  · General protective and hygienic measures:
    Keep away from foodstuffs, beverages and feed.
    Immediately remove all soiled and contaminated clothing.
    Wash hands before breaks and at the end of work.
    Store protective clothing separately.
  · Breathing equipment:
    In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
  · Protection of hands:

  Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material is based on consideration of the penetration times, rates of diffusion and the degradation.
  · Material of gloves
    The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
  · Penetration time of glove material
    The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
  · Eye protection:

  Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties
  · General Information
    · Appearance:
      · Form: Consepsis V: Clear medium viscosity liquid
                  Consepsis: Clear to Cloudy low viscosity liquid
      · Color: Blue Green
                  Green
      · Odor: Mint
      · Odor threshold: Not determined.
    · pH-value at 20 °C: 5.2-6.2
  · Change in condition
    · Melting point/Melting range: Undetermined.
    · Boiling point/Boiling range: Undetermined

(Contd. on page 6)
Safety Data Sheet
acc. to OSHA HCS

Trade name: Consepsis™, Consepsis™ V

(Contd. of page 5)

· Flash point: 36 °C
· Flammability (solid, gaseous): Not applicable.
· Decomposition temperature: Not determined.
· Auto igniting: Product is not selfigniting.
· Danger of explosion: Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

· Explosion limits:
  Lower: 3.3 Vol %
  Upper: 19 Vol %
· Vapor pressure at 20 °C: 552 hPa
· Density at 20 °C: 0.99-1.02 g/cm³
  · Relative density Not determined
  · Vapor density Not determined.
  · Evaporation rate Not determined.
· Solubility in / Miscibility with Water: Not miscible or difficult to mix.
· Partition coefficient (n-octanol/water): Not determined.
· Viscosity:
  Dynamic: Not determined.
  Kinematic: Not determined
· Solvent content:
  Water: <80 %
  VOC content:
    0.00 %
    15.7 g/l / 0.13 lb/gal
· Solids content: <40.0 %
· Other information No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.
· Chemical stability
· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
· Possibility of hazardous reactions No dangerous reactions known.
· Conditions to avoid
  Heat
  Ignition sources
  Flames
· Incompatible materials: No further relevant information available.
· Hazardous decomposition products:
  Oxides of Carbon
  Nitrogen oxides
  Hydrogen chloride (HCl)
  Ammonia

(Contd. on page 7)
### Toxicological information

#### Information on toxicological effects

#### Acute toxicity:

#### LD/LC50 values that are relevant for classification:

<table>
<thead>
<tr>
<th>ATE (Acute Toxicity Estimate)</th>
<th>Oral LD50 &amp; LC50/4 h</th>
<th>Inhalative LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol (64-17-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>5,600 mg/kg (Guinea pig)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3,400 mg/kg (mouse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7,060 mg/kg (rat)</td>
<td></td>
</tr>
<tr>
<td>Inhalative</td>
<td>&gt;10,000 mg/l (Fish)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>39 mg/l (mouse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20,000 mg/l (rat)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Polyethylene Glycol (25322-68-3)</th>
<th>Oral LD50 &amp; LC50/4 h</th>
<th>Inhalative LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>19,600 mg/kg (Guinea pig)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>17,300 mg/kg (mouse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;10,000 mg/kg (rat)</td>
<td></td>
</tr>
<tr>
<td>Inhalative</td>
<td>&gt;100 mg/l (Fish)</td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>&gt;20,000 mg/kg (rabbit)</td>
<td></td>
</tr>
<tr>
<td>LC50(Daphnia magna)</td>
<td>&gt;10,000 mg/l (Water Flea)</td>
<td>Toxicity to aquatic invertebrates</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Peppermint (8006-90-4)</th>
<th>Oral LD50</th>
<th>Inhalative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2,490 mg/kg (mouse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2,426 mg/kg (rat)</td>
<td></td>
</tr>
</tbody>
</table>

#### Primary irritant effect:
- **on the skin**: No irritant effect.
- **on the eye**: No irritating effect.
- **Sensitization**: Sensitization possible through skin contact.
- **Additional toxicological information**: The product shows the following dangers according to internally approved calculation methods for preparations:
  - **Irritant**
  - **Carcinogenic categories**
    - **IARC (International Agency for Research on Cancer)**
      - Ethyl Alcohol (64-17-5) 1
      - FD&C Green 3
    - **NTP (National Toxicology Program)**
      - None of the ingredients is listed.
    - **OSHA-Ca (Occupational Safety & Health Administration)**
      - None of the ingredients is listed.
12 Ecological information

- Toxicity
  - Aquatic toxicity:
    - 64-17-5 Ethyl Alcohol
      - Algae Toxicity: 1,000 mg/l (Algae)
  - Persistence and degradability: No further relevant information available.
  - Behavior in environmental systems:
  - Bioaccumulative potential: No further relevant information available.
  - Mobility in soil: No further relevant information available.
  - Additional ecological information:
  - General notes:
    - Water hazard class 1 (Self-assessment): slightly hazardous for water
    - Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.
  - Other adverse effects: No further relevant information available.

13 Disposal considerations

- Waste treatment methods
- Recommendation:
  - Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packagings:
- Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT, IMDG, IATA: UN1987

- UN proper shipping name
  - DOT: Alcohols, n.o.s. (Ethyl Alcohol)
  - IMDG, IATA: ALCOHOLS, N.O.S. (Ethyl Alcohol)

- Transport hazard class(es)
  - DOT
    - Class: 3 Flammable liquids
    - Label: 3
### IMDG, IATA

- **Class**: 3 Flammable liquids  
- **Label**: 3  
- **Packing group**: Not applicable.  
- **DOT, IMDG, IATA**: III  
- **Environmental hazards**: Not applicable.  
- **Special precautions for user**: Warning: Flammable liquids  
- **Danger code (Kemler)**: 30  
- **EMS Number**: F-E,S-D  
- **Stowage Category**: A  
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**: Not applicable.  
- **Transport/Additional information**:  
  - **DOT**: On passenger aircraft/rail: 60 L  
    On cargo aircraft only: 220 L  
  - **IMDG**: 5L  
  - **Limited quantities (LQ)**  
  - **Excepted quantities (EQ)**: Code: E1  
  - ** Maximum net quantity per inner packaging**: 30 ml  
  - ** Maximum net quantity per outer packaging**: 1000 ml  
- **UN "Model Regulation"**: UN 1987 ALCOHOLS, N.O.S. (ETHYL ALCOHOL), 3, III

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
  - **Sara**: None of the ingredients is listed.  
  - **Section 355 (extremely hazardous substances)**: None of the ingredients is listed.  
  - **Section 313 (Specific toxic chemical listings)**: None of the ingredients is listed.  
  - **TSCA (Toxic Substances Control Act)**: All ingredients are listed.  
  - **TSCA new (21st Century Act) (Substances not listed)**: Dimethicone  
  - **Proposition 65**: None of the ingredients is listed.  
- **Chemicals known to cause cancer**: None of the ingredients is listed.  
- **Chemicals known to cause reproductive toxicity for females**: None of the ingredients is listed.
### Trade name: Consepsis™, Consepsis™ V

<table>
<thead>
<tr>
<th>Chemicals known to cause reproductive toxicity for males:</th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the ingredients is listed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemicals known to cause developmental toxicity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 Ethyl Alcohol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Carcinogenic categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>• EPA (Environmental Protection Agency)</td>
</tr>
<tr>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>• TLV (Threshold Limit Value established by ACGIH)</td>
</tr>
<tr>
<td>64-17-5 Ethyl Alcohol A3</td>
</tr>
<tr>
<td>• NIOSH-Ca (National Institute for Occupational Safety and Health)</td>
</tr>
<tr>
<td>None of the ingredients is listed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GHS label elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazard pictograms</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHS02, GHS07, GHS08</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signal word</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warning</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazard-determining components of labeling:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethicone</td>
</tr>
<tr>
<td>Oils, Peppermint</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazard statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammable liquid and vapor.</td>
</tr>
<tr>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>Suspected of damaging fertility or the unborn child.</td>
</tr>
<tr>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Precautionary statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>If medical advice is needed, have product container or label at hand.</td>
</tr>
<tr>
<td>Keep out of reach of children.</td>
</tr>
<tr>
<td>Read label before use.</td>
</tr>
<tr>
<td>Obtain special instructions before use.</td>
</tr>
<tr>
<td>Do not handle until all safety precautions have been read and understood.</td>
</tr>
<tr>
<td>Keep away from heat/sparks/open flames/hot surfaces. - No smoking.</td>
</tr>
<tr>
<td>Keep container tightly closed.</td>
</tr>
<tr>
<td>Ground/bond container and receiving equipment.</td>
</tr>
<tr>
<td>Use explosion-proof electrical/ventilating/lighting/equipment.</td>
</tr>
<tr>
<td>Use only non-sparking tools.</td>
</tr>
<tr>
<td>Take precautionary measures against static discharge.</td>
</tr>
<tr>
<td>Do not breathe dust/fume/gas/mist/vapors/spray.</td>
</tr>
<tr>
<td>Contaminated work clothing must not be allowed out of the workplace.</td>
</tr>
<tr>
<td>Wear protective gloves/protective clothing/eye protection/face protection.</td>
</tr>
<tr>
<td>If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.</td>
</tr>
<tr>
<td>IF exposed or concerned: Get medical advice/attention.</td>
</tr>
<tr>
<td>Get medical advice/attention if you feel unwell.</td>
</tr>
<tr>
<td>If skin irritation or rash occurs: Get medical advice/attention.</td>
</tr>
<tr>
<td>Wash contaminated clothing before reuse.</td>
</tr>
<tr>
<td>In case of fire: Use for extinction: CO2, powder or water spray.</td>
</tr>
<tr>
<td>Store in a well-ventilated place. Keep cool.</td>
</tr>
<tr>
<td>Store locked up.</td>
</tr>
<tr>
<td>Dispose of contents/container in accordance with local/regional/national/international regulations.</td>
</tr>
</tbody>
</table>
Safety Data Sheet
acc. to OSHA HCS

Trade name: Consepsis™, Consepsis™ V

Chemical safety assessment:
Device is biocompatible when used as directed by dental professionals per ISO 10993-1

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Department issuing SDS: Regulatory Affairs
- Contact: Customer Service
- Date of preparation / last revision 04/29/2019 / -
- Abbreviations and acronyms:
  - IMDG: International Maritime Code for Dangerous Goods
  - DOT: US Department of Transportation
  - IATA: International Air Transport Association
  - ACGIH: American Conference of Governmental Industrial Hygienists
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - ELINCS: European List of Notified Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - NFPA: National Fire Protection Association (USA)
  - HMIS: Hazardous Materials Identification System (USA)
  - VOC: Volatile Organic Compounds (USA, EU)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - NIOSH: National Institute for Occupational Safety
  - OSHA: Occupational Safety & Health
  - TLV: Threshold Limit Value
  - PEL: Permissible Exposure Limit
  - REL: Recommended Exposure Limit
  - Flam. Liq. 3: Flammable liquids – Category 3
  - Skin Sens. 1: Skin sensitisation – Category 1
  - Repr. 2: Reproductive toxicity – Category 2
  - STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2